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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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09/854,671

05/15/2001

Takahiro Ochi

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1143

22428

7590

12/09/2003

FOLEY AND LARDNER
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3000 K STREET NW
WASHINGTON, DC 20007

EXAMINER

SAUCIER, SANDRA E

ART UNIT

PAPER NUMBER

1651

DATE MAILED: 12/09/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/854,671

Applicant(s)

OCHI, TAKAHIRO

Examiner

Sandra Saucier

Art Unit

1651

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 September 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-42 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on 15 May 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 8/13, 10/23
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Claims 1-42 are pending and are considered on the merits.

Claim Rejections – 35 USC § 103

Claims 1-42 are/remain rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,340,648 [A] or WO 93/04013 [A2] in combination with Chistolini *et al.* [U] or Itokazu *et al.* [V].

The claims are directed to an article comprising a porous body of sintered calcium phosphate with globular pores with a porosity of 55-8%, a mean pore diameter of 50-800 microns, including a plurality of large pores having at least three communicating pores of not less than 5 micron diameter and at least one of the communicating pores having a diameter of 25 microns, wherein the total of the open areas is not more than 50% of the pore area, and the pores contain various cells and a method of making the article.

The references are relied upon as explained below.

WO 93/04013 discloses a method of making a sintered porous article for replacing a body member comprising hydroxyapatite, see examples III, VIII and page 10, middle paragraph.

US 6,340,648 discloses an implant comprising an inner part and an outer calcium phosphate sintered part with a porosity of 55-90% with a pore diameter of 150 microns or more and interconnecting pores. The article is formed by foaming with a resin and sintering. The article may be impregnated with a drug, see entire patent.

Itokazu *et al.* disclose that porous hydroxyapatite may be loaded with antibiotic or anticancer drugs prior to implantation.

Chistolini *et al.* disclose that porous hydroxyapatite may be loaded with cells prior to implantation.

The addition of cells into the porous implant disclose in WO 93/04013 or US 6,340,648 would have been obvious when taken with Itokazu *et al.* or Chistolini *et al.* who disclose such an addition.

Response to Arguments

Applicant's arguments filed 9/13/03 have been fully considered but they are not persuasive.

Applicant argues that WO 93/04013 is silent as to pore size and distribution. While this statement may be true, applicant has not distinguished the claimed product from the disclosed product on the record. It is the examiner's position that the disclosed article is formed from the same materials using a similar process and is intended for the same use as the instantly claimed product. Therefore, it is reasonable to assume that the characteristics of the disclosed product are the same or very similar to the claimed product.

Likewise, US 6,340,648 has a porosity of 68%, average pore diameter of 200 microns and an average diameter of communicating parts of 68 microns (example 4). While it may be silent with regard to some elements of the claimed article, it is formed by the same or a substantially similar method and is used for the same purpose as the instantly claimed article. Therefore, it is reasonable to assume that the characteristics are the same or very similar to the instantly claimed article.

The Patent and Trademark Office is not equipped to conduct experimentation in order to determine whether or not applicant's article differs and, if so, to what extent from the articles discussed in the references. Accordingly, it has been established that the prior art articles, which have the same composition and share the property of being used for the same purpose, demonstrate a reasonable probability that it is either identical or sufficiently similar that whatever differences exist are not patentably significant.

Therefore, the burden of establishing novelty or unobviousness by objective evidence is shifted to applicants.

Merely because a characteristic of an article is not disclosed in a reference does not make the claimed article patentable. The known article possesses inherent characteristics which might not be displayed in the tests used the reference. However, the article disclosed may be the same article as claimed.

One of ordinary skill in the art would have been motivated at the time of invention to make this addition of cells to the porous implant in order to obtain the resulting composition as suggested by the references with a reasonable expectation of success. The claimed subject matter fails to patentably distinguish over the state of the art as represented by the cited references. Therefore, the claims are properly rejected under 35 U.S.C. § 103.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

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Art Unit: 1651

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To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1651. The supervisor for 1651 is M. Wityshyn, (703) 308-4743. The normal work schedule for Examiner Saucier is 8:30 AM to 5:00 PM Monday and Tuesday and 8:30 AM to noon on Wednesday.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sandra Saucier whose telephone number is (703) 308-1084. Status inquiries must be directed to the Customer Service Desk at (703) 308-0197 or (703)-308-0198. The number of the Fax Center for the faxing of official papers is (703) 872-9306.

A handwritten signature in black ink, appearing to be 'Sandra Saucier', with a stylized, flowing script.

Sandra Saucier
Primary Examiner
Art Unit 1651
December 4, 2003